



Patient Information Sheet

Fluoxetine hydrochloride (marketed as Prozac)

This is a summary of the most important information about fluoxetine. For details, talk to your healthcare professional.

FDA ALERT [05/2005]-Suicidal Thoughts or Actions in Children

Patients with depression or other mental illnesses often think about or attempt suicide. Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior should be evaluated by their healthcare professional right away.

FDA has approved fluoxetine for treating children who have depression or obsessive-compulsive disorder.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What Is Fluoxetine?

Fluoxetine is in a class of medicines called selective serotonin reuptake inhibitors (SSRIs). Fluoxetine is used to treat Depression, Obsessive-Compulsive Disorder (OCD), Bulimia Nervosa, and Panic Disorder.

Who Should Not Take Fluoxetine?

Never take fluoxetine if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking an MAOI in the last 14 days. Taking fluoxetine close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- **High body temperature**
- **Coma**
- **Seizures (convulsions)**

Do not take a MAOI within 5 weeks of stopping fluoxetine. MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

Never take fluoxetine if you are taking Mellaril (thioridazine), used to treat schizophrenia. Also, do not take Mellaril within 5 weeks of stopping fluoxetine. Taking fluoxetine close in time to Mellaril can result in serious heart beat problems.

What Are The Risks?

- **Suicidal thoughts or actions:** See FDA Alert.
- **Stopping fluoxetine:** Do not stop taking fluoxetine suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.
- **Rash and possible allergic reactions:** Fluoxetine may cause serious skin, lung and allergic-type reactions. Contact your healthcare professional right away if you get

a skin rash or hives, have problems breathing, or get swelling of your tongue, lips, or throat.

- **Bleeding problems:** fluoxetine may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen or naproxen), or other drugs that affect bleeding.
- **Mania:** You may become hyperactive, excitable or elated.
- **Seizures:** You may experience a seizure (convulsion), even if you are not taking fluoxetine close in time with a MAOI.
- **Weight loss:** Fluoxetine can cause weight loss. Children who take it for a long time should have their growth and body weight measured regularly.
- **Pregnancy:** Tell your healthcare professional if you are or may be pregnant because babies delivered to mothers taking fluoxetine late in pregnancy have developed problems, such as difficulty breathing and feeding.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Other side effects** include nausea, difficulty sleeping, anxiety, nervousness, and sleepiness.
- **Tell your healthcare professional** about all your medical conditions, especially if you have liver or heart disease, or diabetes. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs or Foods?

- Do not take fluoxetine with Sarafem (fluoxetine hydrochloride), a drug used to treat PreMenstrual Dysphoric Disorder (PMDD), because they are very similar and you could get an overdose.
- Fluoxetine may interact with medicines other than the ones already mentioned in this information sheet, causing serious side effects. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take, especially:
 - Those that affect bleeding
 - Those used to treat diabetes, seizures, anxiety, mental illness, or depression
- If you plan to drink alcohol, talk to your healthcare professional.

How Do I Take Fluoxetine?

- Fluoxetine is taken by mouth, with or without food, exactly as prescribed by your healthcare professional.
- Take the weekly version of fluoxetine only once a week. Do not start until 7 days after you've taken the last dose of the daily fluoxetine.

Is There Anything Else I Need To Know?

You can get more information about antidepressants at:
<http://www.fda.gov/cder/drug/antidepressants/default.htm>

Prozac FDA Approved 1987

Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570

Druginfo@cder.fda.gov





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